

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen Watmind Medical Co., Ltd. 8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community Kengzi subdistrict, Pingshan District 518118 Shenzhen P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of in-vitro diagnostic Medical Devices (see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2020-12-30

Certificate Registration No.:

SX 60150107 0001

An audit was performed. Report No.: 17054604 003

This Certificate is valid until:

2022-07-03

Certification Body



Date 2020-12-30



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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1 Rev. 0

Attachment to Certificate

Registration No.:

SX 60150107 0001

Report No .:

17054604 003

Organization:

Shenzhen Watmind Medical Co., Ltd. 8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community Kengzi subdistrict, Pingshan District 518118 Shenzhen

P.R. China

Scope:

Products:

In-vitro diagnostic analyzers and in-vitro diagnostic test kits used in the diagnosis and quantitive detection of cardiac markers, immune status, Thyroid Functions, Auto-Immune Diseases, Fertility testings, Coagulation and Infectious Diseases including point of care in-vitro diagnostic medical devices

Sites included:

Shenzhen Watmind Medical Co., Ltd.

8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi subdistrict, Pingshan District, 518118, Shenzhen, China

Manufacture of the a.m. products

Shenzhen Watmind Medical Co., Ltd. Room 106-1 & 107, Shenzhen IC Design & Application

Industrial Park, No. 1089 Chaguang Road, Nanshan District,

Shenzhen, China

Design and Development and Distribution of the a.m. products

Certification Body



Date: 2020-12-30

